Are pulmonary function test suitable to support the choice for a dental brace treatment in patients with sleep apnea?

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The difference in resistance and flow parameters obtained by spirometry, forced oscillation technique (FOT) and negative expiratory pressure (NEP) in protrusion and retraction of the mandible in OSAS patients are predictive parameters for successful...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22296

Bron
Nationaal Trial Register

Verkorte titel
PUMA

Aandoening

Obstructive Sleep Apnea
Mandibular Advancement Thearpy

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Postbus 50 000
7500 KA Enschede
053 487 20 00
Overige ondersteuning: initiator sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The diagnostic accuracy, expressed as sensitivity, specificity, negative predictive value and positive predictive value, for the different measurement parameters. The parameters of the different measurements are:
- Spirometry: absolute difference between the ratios of the expiratory flow rate at 50% of vital capacity to the inspiratory flow rate at 50% of vital capacity (MEF50:MIF50) obtained by the MAD in maximal retracted and maximal protrusive position.
- FOT: absolute difference between the mid-frequency resistances (R20) obtained by the MAD in maximal retracted and maximal protrusive position.
- NEP: absolute difference in flow drops (ΔV ̇) as a percentage of the peak flows (%Vpeak) obtained by the MAD in maximal retracted and maximal protrusive position.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study, 25 patients with obstructive sleep apnea (OSAS) are included. An adjustable mouthpiece will be applied during three different pulmonary function tests: a spirometry, a forced oscillation technique (FOT) and a negative expiratory pressure (NEP). The measurements are performed twice while the subject is lying on his/her back; with the mandible completely protruded and with the mandible completely retracted. The main study objective is to investigate the diagnostic accuracy, expressed as the sensitivity, specificity, negative predictive value and positive predictive value of resistance and flow parameters obtained by spirometry, FOT, and NEP both in protrusion and retraction of the mandible in OSAS patients for the prediction of successful MAD therapy compared to a poly(somno)graph

Doel van het onderzoek

The difference in resistance and flow parameters obtained by spirometry, forced oscillation technique (FOT) and negative expiratory pressure (NEP) in protrusion and retraction of the mandible in OSAS patients are predictive parameters for successful mandibular advancement device (MAD) therapy.

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

Patients will visit the hospital where the three measurements will be performed. Before the

measurements are performed, the demographic data is obtained. The measurements are divided into three different measurements: the forced oscillation technique (FOT), negative expiratory pressure (NEP) and the spirometry. During the measurements the patients is wearing an adjustable mouthpiece to enable protrusion and retraction of the mandible. All the measurements are perfored with the mandible in the maximal comfortable retracted and maximal comfortable protrusive position. The measurements are performed while the patient is laying on his back on a flat examination bench with the legs uncrossed. After the three different measurements in lying position, a standard spirometry in sitting position is performed. The vital capacity is measured and also the forced vital capacity during a forced maximal inspiration and expiration. At the end the patient is asked to answer some questions to evaluate their experience with the different measurements.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Obstructive Sleep Apnea (OSAS) patients with an age of ≥ 18 years.

Apnoea-hypopnoea index (AHI) ≥ 15

Signed informed consent prior to participation.

Scheduled a control poly(somno)graph after titration of mandibular advancement device (MAD) therapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Inability to read and/or understand the Dutch language.

Having a control polygraph after an initial polysomnography

Having a control polysomnography after an initial polygraph

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48021
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7441
NTR-old	NTR7683
CCMO	NL67820.044.18
OMON	NL-OMON48021

Resultaten

Samenvatting resultaten
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